K030555

APR 11 2003

Summary of Safety and Effectiveness

GPS™ Platelet Separation Kit with Anticoagulant ACD-A

Applicant/Sponsor: Biomet, Inc.
P.O. Box 587
56 East Bell Drive
Warsaw, IN 46581-0587

Contact Person: Lonnie Witham
Phone: (574) 267-6639
Fax: (574) 372-1683 E-mail: lonnie.witham@biometmail.com

Trade Name: GPS™ Platelet Separation Kit with Anticoagulant ACD-A

Common name: Centrifuge accessories

Classification Name: Centrifuges (micro, ultra, refrigerated) for clinical use – accessory kit

Legally Marketed Devices to Which Substantial Equivalence is Claimed:
The predicate device is the PCCS Platelet Concentrate Separation Kit previously cleared by 510(k) notification (K021927 - July 12, 2002, Biomet Inc.) Piston syringes were also previously cleared as Bone Graft Delivery System by 510(k) notification (K021071 – July 1, 2002)

The anticoagulant is being included in the kit for the convenience of the user. The user of the predicate device procured anticoagulant separately.

Device Description
The GPS™ separation kit aids separation of the patient's own blood components by density through the use of the GPS™-Thermo International Equipment Company (IEC) centrifuge. The GPS™ separation kit permits platelet rich plasma to be rapidly prepared from a small volume of the patient's blood that is drawn at the time of treatment.

Kit Components: 18 gauge x 1" x 12'' apheresis needle, 16 gauge centesis needle 1 ¼" catheter, 60 ml piston syringe, 30 ml piston syringe, 1 ml piston syringe, petri dish, rubber tubing tourniquet, gauze pad, alcohol pad, adhesive tape, silicone tube, volume gauge, PETG tray with sealed Tyvek® lid, 50 ml bottle of anticoagulant citrate dextrose solution, U.S.P., Solution A (ACD-A).

Intended Use:

The GPS™ Platelet Separation Kit is designed for use in the clinical laboratory or intra-operatively at point of care, for the safe and effective preparation of platelet poor plasma and platelet concentrate from a small sample (50-60 ml) of whole blood.

Summary of Technologies:

The device has the same technological features as other tabletop centrifuge systems previously cleared by the FDA via the 510(k) process. This accessory kit consists of standard marketed devices including syringes, needles, gauze, adhesive tape, alcohol pad, rubber tubing tourniquet, petri dish, and centrifuge blood processing disposable container used to draw and process a small sample of whole blood. The blood is spun in a centrifuge to produce platelet rich plasma. The centrifuge system has similar technological features as the predicate device cleared in K994841.

Non-Clinical Testing:

The original manufacturer, Cytosol Laboratories, Inc, performed relevant testing for the anticoagulant.

Biomet testing was submitted in the predicate 510(k) notification (K021927) including functional testing on bovine and human blood. The platelet count results verified that the predicate device produced platelet rich plasma at a concentration that was equal to or greater than other devices cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Lonnie Witham
Biomet Inc.
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46581-0587

APR 11 2003

Re: k030555
Trade/Device Name: GPS™ Platelet Separation Kit with Anticoagulant ACD-A
Regulation Number: 21 CFR § 862.2050
Regulation Name: General purpose laboratory equipment labeled or promoted for a specific medical use
Regulatory Class: I
Product Code: JQC
Dated: February 18, 2003
Received: February 20, 2003

Dear Mr. Witham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of In Vitro Diagnostic Device Evaluation and Safety has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings and Precautions section of the device's labeling:

> The safety and effectiveness of this device for in vivo indications for use has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific information about the application of other labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

S. Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K030555

Device Name: GPS™ Platelet Separation Kit with Anticoagulant ACD-A

Indications for Use:
The GPS™ Platelet Separation kit is designed for use in the clinical laboratory or intra-operatively at point of care, for the safe and effective preparation of platelet poor plasma and platelet concentrate from a small sample (50-60 ml) of whole blood. The plasma and concentrated platelets can be used for diagnostic tests.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Josephine Bartoli
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030555